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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/864,083	05/23/2001	Mitchell S. Wortzman	01-40076-US	1801

7590

04/23/2003

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EXAMINER

KIM, VICKIE Y

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 04/23/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/864,083

Applicant(s)

WORTZMAN ET AL.

Examiner

Vickie Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3-11 6) ☐ Other: ____

DETAILED ACTION

Status of application

1. Acknowledgement is made of amendment filed April 01, 2003.
2. The claims 24-116 are canceled and the pending claims 1-23 are presented for the examination.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
5. Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon(US 5,932,612) alone.

Gordon teaches a skin lightening composition for the treatment of hyperpigmentation comprising a dermally available derivative of ascorbic acid such as

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magnesium ascorbyl phosphate(a cationic salt of acidic ascorbyl ester, 0.05-10%), sodium bisulfite(water-soluble antioxidant, 0.15%) and hydroquinone(1.5-4%) as active agents, see entire text including table 1 at column 2, especially column 1, lines 65-66 and claims 1, 18 and 21. Gordon teaches most critical elements required by the instant claims except the pH of the said composition, a sodium metabisulfite(recited in claims 11-13 and 19-20), aminopropyl ascorbyl phosphate(recited in claims 21-22) and a sodium ascorbyl phosphate(recited in claim23).

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the pH to about 5.5 to about 8.0 because it is conventional knowledge that the physiological skin pH is about 6.5-7.5. One would have been motivated to make such substitution, with reasonable expectation of success, because best results can be obtained from the dermatological product having ideal pH, closed to the physiological pH. The substitution (i.e. sodium bisulfite or magnesium ascorbyl phosphate with sodium metabisulfite and aminopropyl or sodium ascorbyl phosphate, respectively) is considered to be well within the skilled level of the artisan wherein said substitution is conventionally practiced by a skilled artisan having ordinary skill in the art because each corresponding compounds are old and well known(utilized) in the art where one would have been motivated to make such substitution, with reasonable expectation of success, because they share very same chemical structures and pharma-cores(that is responsible for the therapeutic effects) and similar physical properties, absent evidence to the contrary. One would have been motivated to make such substitution because it is always desired to have more starting materials to make

the manufacture process efficient (e.g. easy accessibility and cost-reduction); and the dermatological skin product having physiological pH is considered to be most ideal due to less skin irritation where one would have expected the improvement of overall therapeutic efficacy because reduced side effects are directly influencing patient's compliance and satisfaction.

6. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lukenbach et al (US 5980871) in view of Gordon(US 5,932,612).

Lukenbach et al teach two separate skin composition using magnesium ascorbyl phosphate(3%) or hydroquinone(2%) as an active skin whitening agent wherein the pH of each composition is adjusted to 7.5. Furthermore, each patented composition utilizes very same vehicles to make up the skin whitening composition and also utilizes very same additives(e.g. antioxidants in water phase(water-soluble)), see examples 100b-100c at column 16.

Applicant's claims differ in that they require both ingredients together in one final product, and optionally with sodium metabisulfite.

As mentioned immediately above in 103 rejection(supra), Gordon teaches a skin whitening composition using magnesium ascorbyl phosphate(0.05-10%), sodium bisulfite(0.15%) and hydroquinone(1.5-4%) together as active agents.

Thus, one would have been motivated to combine these ingredients together to improve the quality as suggested in the Gordon's reference, wherein the combination lacks unwanted side effects associated with hydroquinone while it provides a treatment for hyperpigmentation that is at least as effective as hydroquinone. One would have

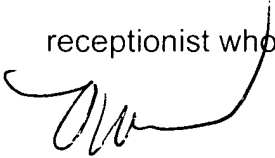
been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same (or similar) ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

For these reasons, the claimed subject matter is not considered to be patentably distinct over the prior art of the record, and thus, the claims are properly included in this rejection.

Conclusion

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Vickie Kim,
Patent examiner
April 18, 2003
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